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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,112

08/02/2005

Takanori Miyoshi

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

CHRISS, JENNIFER A

ART UNIT

PAPER NUMBER

1786

NOTIFICATION DATE

DELIVERY MODE

01/19/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No. 10/544,112	Applicant(s) MIYOSHI ET AL.	
	Examiner JENNIFER A. CHRISS	Art Unit 1786	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Applicant's Amendments and Accompanying Remarks, filed November 10, 2010, have been entered and have been carefully considered. Claims 1 and 6 are amended, claims 5 and 9 are cancelled, claims 11 – 13 are withdrawn and claims 1 – 4, 6 – 8 and 10 – 13 are pending. In view of Applicant's amendment to the independent claims requiring "the porous fiber has internal pores", the Examiner withdraws all previously set forth rejections as detailed in the previous Office Action. The invention as currently claimed is not found to be patentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 – 4, 6 – 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2003/0146532) in view of the article entitled "Electrospun nanofibrous structure: A novel scaffold for tissue engineering" by Wan-Ju Li et al.

Chen et al. is directed to a process for preparing porous bioresorbable material having interconnected pores (Title) suitable for cell growth and nutrient transfer to the cells and metabolic waste expelled from the pores [0023 - 0024]. .

Chen et al. teach a material formed from a bioresorbable polymer and a low molecular weight oligomer where the oligomer has a molecular weight of 200 to 4000 and the mixture is dissolved in an organic solvent to form a solution and then the polymer solution is contacted with a coagulant to form a porous bioresorbable material [0026]. The bioresorbable polymer can be polycaprolactone, polylactic acid, etc. [0035], the low molecular weight oligomer can be polyethylene glycol or polypropylene glycol [0036] and the solvent can be chloroform, etc. [0037]. Although it should be noted that the final product is claimed and the hydrophobic solvent-soluble polymer need only be hydrophobic solvent soluble and does not actually require the particular solvent. Chen et al. note that the porosity and pore size of the finally formed porous material can be adjusted by means of choosing the species and molecular weight of the low molecular weight oligomer and the content in the bioresorbable polymer solution [0041]. In Example 12, 15 g of polycaprolactone, 7 g of polycaprolactone triol and 8 g of polyethylene glycol having a molecular weight of 300 were added to DMF to create a solution and then coagulated to form a porous PCL material [0058].

Chen et al. fail to teach that the porous bioresorbable material is made into a fiber having an average fiber diameter of 0.1 to 20 microns.

The article entitled "Electrospun nanofibrous structure: A novel scaffold for tissue engineering" is directed to creating an electrospun fibrous structure for tissue-

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engineering applications made from PLGA fibers having a range of diameters from 500 to 800 nm (0.5 - 0.8 microns) which has a morphologic similarity to the extracellular matrix of natural tissue which is characterized by a wide range of pore diameter distribution, high porosity and effective mechanical properties. The electrospun nanofibrous structure is capable of supporting cell attachment and proliferation (Abstract). The ultimate goal of the scaffold design is the production of an ideal structure that can replace the natural ECM until host cells can repopulate and resynthesize a new matrix (page 613, paragraph 3). The dimensions of the building components of the scaffold are important factors in regulating cell activities (page 614, paragraph 2). In connective tissue, ECM is composed of two main classes of macromolecules, ground substances and fibrous proteins that together form a composite-like structure. Collagens embedded in proteoglycans maintain structural and mechanical stability. The collagen fibrous structure is organized in a three-dimensional fiber network composed of collagen fibers that are formed hierarchically by nanometer-scale multi-fibrils. Therefore, ideally, the dimensions of the building blocks of a tissue-engineering scaffold should be on the same scale with those of natural ECM (page 614, paragraph 3). The nanofibrous structure produced by electrospinning has a high surface to volume ratio, providing more substrate for cell attachment (and therefore a higher cell density per unit of space) compared to other structures (page 614, paragraph 5).

It would have been obvious to one of ordinary skill in the art to use the porous bioresorbable material having interconnected pores of Chen et al. to make a nanofibrous matrix of fibers having a diameter of 0.5 to 0.8 microns as suggested by the

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article motivated by the desire to create a synthetic scaffolding which has properties and architecture similar to natural ECM which allows for high cell attachment.

Response to Arguments

5. Applicant's arguments with respect to claims 1 – 4, 6 – 8 and 10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CHRISS whose telephone number is

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(571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Chriss/
Primary Examiner, Art Unit 1786

/J. A. C./
Primary Examiner, Art Unit 1786